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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|-----------------------------|
| 10/540,266 | 12/07/2005 | Kazushi Oshino | 274296US0PCT | 1439 |
| 22850 | 7590 | 01/22/2010 | | |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | EXAMINER ROBERTS, LEZAH | |
| | | | ART UNIT 1612 | PAPER NUMBER |
| | | | NOTIFICATION DATE 01/22/2010 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/540,266 | Applicant(s) OSHINO ET AL. | |
| | Examiner LEZAH W. ROBERTS | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-13 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10 Nov 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed November 10, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant has amended claim 4 to no longer encompass the elected species comprising components (A), (B) and (C) in the first composition and component (B) in the second composition. Thus, claim 4 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 22, 2009.

Claims

Claim Objection (New Objection)

Claim 13 is objected to because of the following informalities: the claim recites "a phosphor containing compound". It is suggested that "phosphor" be changed to "phosphate". Appropriate correction is required.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

Claims 1-3 and 5-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chow et al. (US 5,891,448) in view of Forward et al. (US 4,193,988, already of record).

Chow et al. disclose two-component fluoride delivery systems. The systems include mouth rinses, dentifrices and chewable tablets. When both components are mixed, they form calcium fluoride (Abstract), encompassing claim 3. One part comprises a fluoride source such as sodium fluoride (col. 7, lines 6-9). A calcium fluoride inhibitor is also present in one or both parts (col. 4, lines 54-56). The second part comprises a calcium salt such as calcium chloride, calcium lactate, and calcium acetate (col. 6, lines 57-60). Calcium fluoride inhibitors include calcium glycerophosphate (col. 7, lines 35-40 and Example V), encompassing claims 9-11. Table 5 discloses a two part composition comprising sodium fluoride in Component A and calcium chloride with glycerophosphate in Component B. The two solutions are mixed and immediately applied to enamel (col. 15, lines 59-61), encompassing claim 2. The reference does not disclose a phosphate compound, encompassing the limitation of the instant claims. The reference differs from the instant claims insofar as it does not disclose a monofluorophosphate supplying compound.

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Forward et al. disclose oral hygiene compositions comprising a mixture of calcium glycerophosphate and sodium monofluorophosphate. The compositions may be formulated into powders, pastes, gels or liquids (Abstract). The activity of sodium monofluorophosphate in reducing the solubility of tooth enamel is enhanced or potentiated when used in admixture with certain proportions of calcium glycerophosphate (col. 1, lines 22-26). The compositions may also comprise other calcium salts. The reference differs from the instant claims insofar as it does not disclose the compositions are two-component systems where sodium fluoride is separated from a calcium salt, a monofluorophosphate salt and polyolphosphate salt.

It would have been obvious to one of ordinary skill in the art to have added sodium monofluorophosphate to the calcium salt/calcium glycerophosphate containing component of the two component system of Chow et al. motivated by the desire to obtain an enhanced reduction of the solubility of tooth enamel when calcium glycerophosphate and sodium monofluorophosphate are mixed together as disclosed by Forward et al.

In regards to claims 6 and 7, it is reasonable to conclude that the compositions of the combined teachings will have these properties because the compositions of the reference may comprise substantially the same components, a calcium ion supplying compound, a fluoride ion supplying compound, a polyolphosphate and a monofluorophosphate, of the instant claims and therefore upon mixing the two components when calcium salts, calcium glycerophosphate, monofluorophosphate and a fluoride such as sodium fluoride are present, calcium fluoride will be formed, as

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disclosed by Chow et al., as well as secondary aggregates of calcium fluoride fine particles in substantially the same proportions.

In regards to claim 5 and the particle size of the calcium fluoride formed from mixing the two components, it is reasonable to conclude that the two components will yield particles the same size as those recited in the instant claims because the same calcium salts and fluoride providing compounds used in the reference are the same and are used in the same amounts as those recited by the instant claims and therefore one of ordinary skill in the art would reasonably conclude that the resulting precipitates will have substantially the same size.

Response to Declaration filed under 37 CFR 1.132

The Declaration filed under 37 CFR 1.132 is sufficient to overcome the rejections over Winston et al. (US 5,817,296) and Ishihara et al. (US 6,770,265).

In regard to the new rejection over Chow et al. in view of Forward et al. cited above, the Declaration is insufficient to overcome the rejection.

Declaration

The Declaration discloses a comparison of two two-component systems, one comprising the components disclosed by Winston et al.'s Example 6 (comprising calcium glycerophosphate, calcium lactate and sodium monofluorophosphate in one part and sodium fluoride and dipotassium phosphate in the other part) and a system the

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same as Example 6 but without a dipotassium phosphate, a component of Winston's invention. It was shown by the Declaration that fluorine adsorption was inhibited by the presence of the phosphate salt.

Examiner's Response to Declaration

These results are insufficient to overcome the new rejection because the combination of references do not disclose the incorporation of any phosphate salts as disclosed by Winston et al. or Ishihara et al. Thus it is reasonable to conclude that the combination would not lead to an inhibition of fluorine absorption because a phosphate salt is not present. Further the reference suggests enhanced fluoride absorption because a combination calcium glycerophosphate and sodium monofluorophosphate is disclosed to enhance the reduction of solubility of tooth enamel. Therefore, the Declaration is insufficient to overcome the new rejection.

Claims 1-3 and 5-13 are rejected.

Claim 4 is withdrawn.

Claim 13 is objected.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612